IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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COMPANY DOE,

*

Plaintiff

vs. * **Civil No.:**_____

INEZ TENENBAUM, in her official capacity as Chairwoman of the Consumer Product Safety Commission, and the CONSUMER PRODUCT SAFETY COMMISSION *

4330 East West Highway,
Bethesda, MD 20814 *

Defendants

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COMPLAINT

This complaint seeks to enjoin an arbitrary, egregious, and unconstitutional exercise of Federal authority whose immediate, continuing and devastating effect on plaintiff and the public at large will be irreparable and irremediable.[1] The Consumer Product Safety Commission intends to publish on its website a report with no identified complaining party that seeks to associate the tragic, but medically unexplained and unexplainable death, of an infant with the use of plaintiff's infant carrier without

[1] Plaintiff has not sought a temporary restraining order because the Commission has agreed to stay publication of the report pending a decision on a motion for preliminary injunction. Plaintiff expects to file a briefing schedule for a preliminary injunction in the near future.

factual, scientific, medical or legal support. The effect of the report's publication will be to indict by association a product whose safety has been uniformly recognized and endorsed, and whose safety performance regarding breathing issues is perfect—not virtually perfect or almost perfect—but perfect after over one million carriers sold over eight years in 20 countries. By publication of the report, the Commission will destroy the brand goodwill and commercial reputation established by plaintiff solely as the result of an incident that was not and cannot be shown to be related to the use of plaintiff's product. In making this determination, the CPSC violated the statute establishing the website and the Commission's own codified rules governing reports to the website.

The statutory vehicle for this gross abuse of power is the newly enacted and highly controversial Commission consumer website which allows "Reports of Harm" related to the use of a consumer product to be posted and thereby broadcast to the world with virtually no regard for the harm such postings will cause to reputable manufacturers. Indeed, one of the Commissioners described the database as "unreliable to the point, essentially, of uselessness. Worse yet, the database will mislead consumers, invade their privacy, waste their tax dollars, and inflict random reputational harm on makers of consumer products."

This initial report has gone through two iterations by the Commission which are materially inaccurate, false, misleading, and bear no relationship to the erroneous report as originally filed. The first version was filed by an undisclosed hearsay source—not the mother who used the infant carrier—who attributed Sudden Infant Death Syndrome ("SIDS") to plaintiff's infant carrier. Without any evidence to support this assumption, the Commission conceded its material inaccuracy; the Commission then proposed a second version linking the infant carrier with "rebreathing in a hot environment." Recognizing the absence of any autopsy findings to support this finding—especially since the mean

temperature on the date and location where the tragic accident occurred was 68 degrees —the Commission has abandoned its second version of the report. The Commission has now presented plaintiff with its third version, which continues to link the infant carrier to the infant's death despite the absence of any causality or association. What began as a concededly materially inaccurate third-party, hearsay report of harm has been transformed into a Commission indictment of a product with a perfect safety record in this regard—without specific cause, association or linkage between the consumer product and the tragic death of an infant. Such an unsupportable, inflammatory report written, not by the "reporter" of injury, but by the Commission itself, is an arbitrary and capricious exercise of statutory authority under the Consumer Product Safety Improvement Act, as codified at 15 U.S.C. Sec. 2055A, and violates the Fifth Amendment of the Constitution.

For all the reasons more fully described below, plaintiff asserts that the publication of this inflammatory and unsupported report in violation of the laws governing the website will cause irreparable harm to the reputation and financial wellbeing of plaintiff and will discourage the public from using a safe and reliable infant carrier.

Plaintiff therefore alleges as follows:

PARTIES

1. Plaintiff, The ERGO Baby Carrier, Inc. ("ERGObaby") is a corporation organized and existing under the laws of the State of Hawaii with its principal place of business in Pukalani, Hawaii. The company manufactures a product used by parents and caregivers of infants. ERGObaby has a uniformly excellent safety record in all the jurisdictions in which it is sold, has passed stringent inspections and secured numerous safety certifications around the world, and has made and continues to make substantial investments in its safety record. ERGObaby has never been sued

(indeed it has never even submitted an insurance claim relating to injury) and has never been subject to any regulatory proceeding regarding safety in any of the twenty or so countries in which it is sold.

2. Defendant Inez Tenenbaum is the Chairwoman of the Consumer Product Safety Commission and performs the majority of her official duties in Bethesda, Maryland. Defendant Consumer Product Safety Commission ("CPSC" or "Commission") is located at 4330 East West Highway in Bethesda, Maryland. The CPSC is responsible for creating and managing the Publicly Available Consumer Product Safety Information Database ("Database"), located at http://www.saferproducts.gov.

JURISDICTION AND VENUE

3. This action arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 553, 701-706, and the Due Process and Takings Clauses of the Fifth Amendment of the United States Constitution.
4. Jurisdiction is conferred on this Court by Title 28 U.S.C. § 1331 providing for original jurisdiction of this Court in cases arising under the Constitution and laws of the United States.
5. Venue is proper in this Court under 28 U.S.C. § 1391(e) because Defendant Consumer Product Safety Commission resides in this judicial district and has its principal offices in Bethesda, Maryland. Defendant Chairman Tenenbaum performs her official duties in this judicial district, and a substantial part of the events or omissions giving rise to this action occurred in this judicial district.

FACTUAL ALLEGATIONS

6. With the Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314 (Aug. 14, 2008), Congress mandated that the Consumer Product Safety Commission create a publicly available database (the "Database") concerning the use of consumer products and other products or substances regulated by the CPSC. .
7. On December 9, 2010, the Commission promulgated a final rule detailing the procedures that would be used once the Database was created; the rule was effective on January 10, 2011.
8. On March 11, 2011, the Database was launched and became accessible to the public at http://www.saferproducts.gov.
9. The Commission has a statutory mandate to ensure that reports published on the database meet minimum requirements for publication, including but not limited to establishing that the injury or risk of injury at issue is "related to" and not simply coincidental with the use of the consumer product. 15 U.S.C. § 2055A(b)(2).
10. The Commission furthermore has a statutory mandate to prevent the publication of materially inaccurate reports. 15 U.S.C. § 2055A(c)(4).
11. On September 9, 2011, an unnamed local government agency submitted an Incident Report (Report No. 20110909-01B19-2147475479) (attached as Exhibit A) in which the agency alleged that ERGObaby's product had caused the death of an infant on May 21, 2011.
12. The Incident Report states that the submitter is a local government agency who was not in possession of the product and did not provide verifiable identifying information about the product.
13. The Incident Report states, "1 month old baby in Arnold Maryland was placed in an Ergo Baby performance carrier – Mom had taken baby out strawberry picking. Mom noted that baby not

breathing. 911 called and CPR started. Baby died. Case went to the Maryland Medical Examiners Office were [*sic*] it was determined baby did not die from any physical/medical causes. Case is being called underdetermined- sudden infant death from the carrier."

14. On September 19, 2011, the Commission transmitted this incident report to ERGObaby.

15. The Commission gave ERGObaby no additional information about the incident.

16. ERGObaby promptly objected to the publication of the report on http://saferproducts.gov in a letter to the Commission dated and delivered on October 3, 2011; the letter outlined the material inaccuracies apparent from the face of the report. (Attached as Exhibit B).

17. The October 3, 2011 letter made plain to the Commission that ERGObaby had a perfect safety record with regard to the issue raised by the incident report; that ERGObaby had not received any reports of incidents like this occurring in eight years of business and over one million products sold; that the admission that the cause of death was undetermined disproved the report's allegation that the death was related to the use of ERGObaby's product; and that the very nature of "sudden infant death" as a diagnosis of exclusion precludes the assignment of causation to ERGObaby's product. Thus, the report, as filed, was incomprehensible and inconsistent on its face; it made no sense and should have been treated by the Commission as such.

18. On October 5, 2011, ERGObaby obtained a copy of the autopsy report for the infant involved in the May 21, 2011 incident. (Attached as Exhibit C).

19. The autopsy report, dated July 27, 2007, clearly states the cause of the infant's death could not be determined and listed the official cause of death as "sudden unexplained death in infancy."

20. On October 7, 2011, ERGObaby transmitted to the Commission a copy of the autopsy report and a report written by Dr. Michael Baden. (Attached as Exhibit C). Dr. Baden, one of the world's

foremost forensic pathologists, is known for his work investigating high-profile deaths and as a host of HBO's *Autopsy*. He is also the Forensic Science Contributor for Fox News Channel. He has been the author or co-author of more than eighty professional articles and books on aspects of forensic medicine. Dr. Baden was the Chief Medical Examiner for the City of New York in 1978-1979, and was Chairman of the Forensic Pathology Panel of the House Select Committee on Assassinations that reinvestigated the John F. Kennedy assassination.

21. Dr. Baden conducted an independent review of the autopsy report and the incident report and, in his report, concluded that the autopsy report did not attribute the infant's death to the use of the ERGObaby's product, writing that "The stated finding of the medical examiners is that the cause of [the child]'s death is unexplained: that they looked for but could find no causal connection between the infant carrier and the cause of death." Dr. Baden's report also concluded that a reference in the autopsy report's comment about rebreathing in a hot environment was purely speculative and not supported by any evidence in the autopsy.

22. On October 13, 2011, the Commission informed ERGObaby via e-mail that the Commission agreed with the material inaccuracy claim that ERGObaby had filed, noting that "The U.S. Consumer Product Safety Commission (CPSC) has determined that the information you identified in Report No. 20110909-D1B19-2147475479 as being materially inaccurate meets the definition of materially inaccurate information set forth in 16 CFR 1102.26." (Attached as Exhibit D).

23. The Commission's decision was not explained with any analysis. The Commission also did not identify what evidence, if any, the Commission relied upon in making its decision.

24. In the same October 13, 2011 e-mail, the Commission informed ERGObaby that it would publish an altered version of the report which would instead remove the line stating "Case is being called underdetermined- sudden infant death from the infant carrier" and replacing it with, "[Their investigation did not indicate positional asphyxia, but rebreathing in a hot environment could have contributed to death. The manner of death was "could not be determined"]. In the regulations at 16 C.F.R. 1102.26(a)(1), "material inaccuracy" is defined as "information that is false or misleading, and which is so substantial and important as to affect a reasonable consumer's decision making about the product." Associating an infant carrier with the death of a child would affect a reasonable consumer's decision making about the product.

25. The same day, on October 13, 2011, ERGObaby submitted a second material inaccuracy claim, noting that the Commission had conceded the material inaccuracy of the first report but compounded the problem by planning to publish a report that included the autopsy report's highly speculative comment that although there was no indication of positional asphyxia, rebreathing and a hot environment could have contributed to death, a claim that was determined speculative and not based on any evidence in the autopsy report, as explained in the report of ERGObaby's medical expert. (Attached as Exhibit E). The letter demanded that the Commission not publish this materially inaccurate, CPSC-version of the report based on a new speculative theory wholly divorced from the SIDS allegation of the first report. The letter further stated that "if the CPSC properly concluded that the linkage between the infant carrier and SIDS was materially inaccurate, it must determine that the current report is equally inaccurate; at least SIDS by definition means that a sudden unexplained death in infancy has occurred." In addition,

the letter refuted the claim of a "hot environment" by noting that the mean temperature for the date and place of the incident was 68 degrees Fahrenheit.

26. On October 15, 2011, the Consumer Product Safety Commission abandoned its second version, conceding in effect that it had no associational link between the carrier and any physical or medical cause of death. Instead, it insists on publishing a final, third version of the incident report.

27. Plaintiff has been advised by counsel for the Commission that the final version of the incident report would state as follows: "1 month old baby in Arnold, Maryland was placed in an Ergo Baby Performance Carrier -Mom had taken baby out strawberry picking. Mom noted that baby not breathing. 911 called and CPR started. Baby died. Case went to the Maryland Medical Examiner's Office where it was determined baby did not die from any physical/medical causes. Case is being called undetermined."

28. Like the previous decision, the Commission's decision was not explained. The Commission also did not identify what evidence, if any, the Commission relied upon in making its decision. The Commission has not identified whether it interviewed family members of the infant who passed away on May 21, 2011 or any witnesses to the event; whether it obtained and reviewed a copy of the police report to the incident; whether it obtained the infant's autopsy report through means other than by plaintiff; whether it engaged medical professionals in reviewing the incident report; or whether it or anyone ever examined the product in question.

29. The language chosen to be included in the third version of the incident report did not come from the unnamed submitter, but rather was written by the Commission itself.

30. The Commission defines materially inaccurate information in a report of harm as: "information that is false or misleading, and which is so substantial and important as to affect a reasonable consumer's decision making about the product, including: (i) The identification of a consumer product; (ii) The identification of a manufacturer or private labeler; (iii) ***The harm or risk of harm related to use of the consumer product***; or (iv) The date, or approximate date on which the incident occurred." (emphasis added).

31. The final version of the report does not correct the material inaccuracies because it continues to falsely imply a link between the use of ERGObaby's product and the death of the infant, making it misleading and therefore materially inaccurate under the regulatory definition of material inaccuracy. Under the Commission's definition of material inaccuracy, both false *and* misleading information constitute material inaccuracy if the information misleads consumers regarding the product's source, the date of the incident, or the harm or risk of harm related to the product's use. 16 CFR 1102.26. The general public goes to http://www.saferproducts.gov to investigate whether or not consumer products have caused, created, or been associated with risks of injuries or death. The availability of this report in that database will imply to the general public that ERGObaby's product caused or was associated with the death of the infant, even though ERGObaby has established and the Commission has admitted that the allegation of such a link is materially inaccurate. This false implication will grossly mislead the public as to the safety of ERGObaby's carriers, which have an exemplary safety record.

32. Although ERGObaby may post a written response ("comment") to the incident report on the saferproducts.gov website, that comment is not sufficient to remove the stigma and harm to ERGObaby that would be caused by posting the incident report on saferproducts.gov.

33. Were the final report found to correct the material inaccuracies, it would still fail to meet the minimum requirements for publication, which require that the report include "A brief narrative description of illness, injury, or death; or risk of illness, injury, or death related to use of the consumer product." 16 CFR 1102.10. The final report states that the child was in an ERGObaby carrier and then died of undetermined causes. This report does not demonstrate that the death was related to the use of the product but merely establishes that the product was present at the scene of the death. Presumably, many other consumer products were present at the scene of the death or used by the child's caregivers on the day of the death, but that does not establish that the death was in any way related to the *use* of those products or the ERGObaby carrier. The fact that the cause of death is expressly found to be undetermined means that the ERGObaby carrier can no more be shown to be "related" to the death than the clothes the child was wearing at the time of death. It is for this reason that Congress required that prior to the publication of any safety report on the website, the CPSC determine that there exists a relationship between the use of a product and the injury, not a happenstance between the presence of the product and the injury.

34. Moreover, the general public perceives the phrase "related to the use of the product" to imply a causal link, which this report fails to establish and cannot establish based on the available evidence about the incident. If the final report were published, it would severely and irreparably damage ERGObaby's business, its reputation for safety, and its business goodwill. The damage to ERGObaby's business, reputation for safety, and business goodwill would be irreparable because even a subsequent removal of the Report from the Database could not remove the report from the public consciousness after consumer groups viewing the database relay the report's contents to consumers. The association of an ERGObaby product and the death of a child on a

public website carrying the imprimatur of the CPSC is a bell that cannot be unrung no matter what curative actions are taken, given the speed with which even unsubstantiated and patently false rumors or theories propagate on the Internet and in other consumer public discourse.

35. The Commission allows persons visiting its website to export a .csv file of the database and all of the reports it contains at the moment of file export. The Commission cannot remove this report from downloaded copies of this .csv file. Therefore, removal of the report from the database after a subsequent determination of material inaccuracy could not repair the harm caused by the initial publication of the report and the downloading of the .csv file to a consumer or other person's personal computer.

36. The edited report also departs so drastically from the originally submitted report that the true author of the report has become the Commission; the report therefore bears the imprimatur of the government, deepening the harm that ERGObaby will suffer.

37. The Commission has provided inconsistent answers about whether an investigation into ERGObaby's products has been commenced. The Commission, at a minimum, has not disclosed to ERGObaby the methods, inquiries, evidence obtained, or result of any investigation into ERGObaby products.

38. In approving the final rules that established the database, one Commissioner stated that the database would be "an early warning system for consumer products" and that "the Commission will, depending on resources, attempt to weed out the obviously inaccurate reports before publication—and in some very obvious cases even before the report is sent to the manufacturer." The website for the database also states that, "[t]hrough SaferProducts.gov, consumers, child service providers, health care professionals, government officials and public safety entities can

submit reports of harm (Reports) involving consumer products." The Commission has not met those obligations with respect to this report. The report does not "involve" a consumer product and the early warning system will only unnecessarily alarm consumers.

39. Given the undeniably severe consequences that publication of the Report would cause plaintiff, and the fact that Congress has mandated that the CPSC must establish a relationship between the use of the product and the injury as a predicate to publication, the utter lack of any meaningful process allowing plaintiff to comprehensively challenge the existence of such a relationship is contrary to the applicable statutes and regulations, violates plaintiff's constitutional rights and is patently unfair, arbitrary and capricious.

COUNT I

(Abuse of Discretion)

40. ERGObaby incorporates by reference paragraphs 1 through 39 of this Complaint as though set forth in full.

41. Under 5 U.S.C. § 706(2)(A), a reviewing court shall hold unlawful and set aside agency action found to be an abuse of discretion.

42. The Commission abused its discretion by failing to reject the September 9, 2011 report as so materially inaccurate that it could not be published even in a corrected form.

43. 15 U.S.C. § 2005A called for the creation of a publically available database on the safety of consumer products; it also mandates that if, prior to publication of a report or a manufacturer comment on a report, the Commission determines that the information in such report or comment is materially inaccurate, the Commission shall either correct the inaccuracy through the deletion or addition of information or decline to add the materially inaccurate information to the database.

44. The Commission's edited versions of the report fail to correct the material inaccuracies of the original report because they continue to falsely imply a relationship between ERGObaby's product and the death of an infant. Although the statute favors correction over non-publication of a materially report where possible, since in this instance the Commission cannot correct this material inaccuracy, it should have declined to add the report to the database. Once the Commission determined that no evidence links SIDS with the infant carrier as charged by the complaining party, the report should have been rejected. The decision to publish rather than "weed out the obviously inaccurate report[]" was an abuse of discretion.
45. The edited versions of the report further fail to meet the minimum requirement that the report of harm be related to the use of a product. The mere presence of a consumer product at the scene of an incident does not establish that the incident was related to the use of the product.
46. By failing to recognize the material inaccuracies in the September 9, 2011 report and deciding to publish the report in the publically available database, the Commission abused its discretion.

COUNT II

(Arbitrary and Capricious)

47. ERGObaby incorporates by reference paragraphs 1 through 46 of this Complaint as though set forth in full.
48. Under 5 U.S.C. § 706(2)(A), a reviewing court shall hold unlawful and set aside agency action found to be arbitrary and capricious.
49. The Commission's failure to declare the September 9, 2011 report to be materially inaccurate and the resulting decision to publish the report was arbitrary and capricious.

50. Under the Commission's own definition of material inaccuracy, the September 9, 2011 report is materially inaccurate because it is false and misleading and the false and misleading information is "so substantial and important as to affect a reasonable consumer's decision about the product."

51. The corrected report fails to correct the material inaccuracy because it falsely implies a link between ERGObaby's product and the death of the infant and therefore remains grossly misleading.

52. By failing to recognize that the initial report was so materially inaccurate that it could not correct the material inaccuracies and further failing to recognize that the edited report was materially inaccurate under the Commission's own definition of material inaccuracy, the Commission acted in an arbitrary and capricious fashion when it decided to publish the edited report.

53. The Commission also acted in an arbitrary and capricious manner by failing to recognize that the edited report does not meet the minimum requirements for publication in the database and deciding to publish the edited report.

54. The Commission also acted in an arbitrary and capricious manner by failing to provide plaintiff with a meaningful procedure to challenge the finding of a relationship between the use of the product and the injury.

COUNT III

(Action in Excess of Statutory Authority)

55. ERGObaby incorporates by reference paragraphs 1 through 54 of this Complaint as though set forth in full.

56. Under 5 U.S.C. § 706(2)(C), a reviewing court shall hold unlawful and set aside agency action found to be in excess of the agency's statutory authority.

57. 15 U.S.C. § 2005A mandates that the Commission create and manage a publically available database regarding "reports of harm relating to the use of consumer products" but requires that the Commission decline to add to the database uncorrected information which the Commission has determined is materially inaccurate information.

58. Under the Commission's own definition and as described in Counts II and III, the information contained in the report is materially inaccurate.

59. As set forth in paragraphs 52 and 53 of this complaint, the edited version of the report fails to correct the material inaccuracy and, alternatively, fails to meet the minimum requirements of publication.

COUNT IV

(Violation of ERGObaby's Fifth Amendment Rights)

60. ERGObaby incorporates by reference paragraphs 1 through 59 of this Complaint as though set forth in full.

61. Under 5 U.S.C. § 706(2)(B), a reviewing court shall hold unlawful and set aside agency action found to be contrary to a constitutional right.

62. The agency's actions deprived ERGObaby of its property rights without reasonable compensation or due process of law, thereby violating the Fifth Amendment to the United States Constitution.

63. ERGObaby has an investment-backed expectation in its business goodwill and reputation for excellent safety, which the publication of this report substantially devalues by falsely implying that ERGObaby's product has caused an infant's death.

64. The Commission deprived ERGObaby of its property but has not provided ERGObaby with due process of the law. The Commission has not provided ERGObaby with adequate notice of the facts involved in the incident report or adequate opportunity to respond to the allegations. In addition, the Commission has substantially ignored ERGObaby's evidence about the central material inaccuracy of the report—the linkage of the product with an infant's death—rendering what little process there has been meaningless.

65. The Commission has further failed to give ERGObaby due process of the law by refusing to give ERGObaby additional time to respond to a materially different report. The Commission must transmit a report to the manufacturer or private labeler ten business days prior to publication in order to give the manufacturer or private labeler time to respond. 15 U.S.C. § 2055A(c)(3). If the Commission has received notification that the report contains material inaccuracies, the Commission must delay the publication of the report for an additional five days. 15 U.S.C. § 2055A(c)(4). As ERGObaby conveyed to the Commission, the edited version of the report remains materially inaccurate but is a substantially different report, necessitating that ERGObaby file an entirely new material inaccuracy claim to object to the publication of the edited report. The Commission has failed to give ERGObaby the statutory ten business day time period in which to review and respond to each of the two new reports and has thereby deprived ERGObaby of due process of the law.

66. The ability of the company to write comments that appear alongside the report is insufficient protection against the irreparable damage this misleading report will cause ERGObaby. The ability to provide comments does not mitigate the Commission's violation of ERGObaby's due process rights because it is not part of the due process given by the Commission to ERGObaby

prior to publication of the report. Due process requires notice and opportunity to respond before the decision-maker; in this case, the Commission is the decision-maker because the Commission decides whether or not to publish the report. The Commission is therefore obligated to provide due process to manufacturers and private labelers. To imply that the opportunity to provide comments that appear alongside the published report provides due process is to suggest that the ultimate decision-maker is the public. The public makes decisions about purchasing and using products but does not decide whether or not a report is published after a material inaccuracy claim is filed.

67. The Commission has also not provided ERGObaby with any compensation for the deprivation of ERGObaby's property rights in its business goodwill and reputation for excellent safety. The Commission's actions therefore violate the Fifth Amendment's Takings Clause.

PRAYER FOR RELIEF

WHEREFORE, for the reasons set forth above, ERGObaby prays for relief as follows:

A. That the Court declare that the Commission's decision to publish the September 9, 2011 or any edited version thereof is arbitrary and capricious, an abuse of an discretion, an exercise of authority exceeding that conferred by the statute calling for the Commission to create and manage the Publically Available Consumer Product Safety Information Database.

B. That the Court declare that the Commission's decision violated ERGObaby's rights under the Due Process Clause and Takings Clause of the Fifth Amendment of the United States Constitution.

C. That the Court set aside the Commission's decision to publish the September 9, 2011 Incident Report and enjoin the publication of the report.

D. That the Court issue a preliminary injunction, and any other relief that the Court deems necessary or appropriate.

Respectfully Submitted,

Dated: October 17, 2011

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